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Synthetic biology innovations need a clearer path to market

By Dominic Basulto October 29

Synthetic biology innovations could be forced to ferment for longer than planned if changes aren't made to the nation's regulations. (Peter DaSilva for The Washington Post)

A new report from the Wilson Center's Synthetic Biology Project highlights the need to modernize the complex and often times contradictory regulatory oversight of the synthetic biology industry. Right now, there's a confusing mix of federal regulators (FDA, USDA and EPA) and an alphabet soup of federal statutes (TSCA, FIFRA, FFDCA, PPA) that result in some synthetic biology products being caught in an innovation no-man's land. And that could impede some promising innovations from reaching the marketplace, especially those from smaller start-ups

Take, for example, something as simple as a genetically modified mosquito that's designed to mitigate human disease. According to the Wilson Center report, even this innovation is "relatively uncharted territory" for federal regulators. When the biotech firm Oxitec designed a genetic technique that would prevent female offspring of certain disease-carrying mosquitoes from reaching maturity, it raised a number of thorny regulatory questions.

If you think of this mosquito innovation as a pest control solution, then the USDA's Animal and Plant Health Inspection Service (APHIS) should be the lead regulator. However, if you think of the genetically modified mosquito as a drug to eliminate a known disease – yellow fever, Dengue fever or Chikungunya – then the FDA should be the lead regulator.

But even here, there's a potential problem, since it's not clear if this should be considered an "animal drug" (in which case it would be regulated by the FDA's Center for Veterinary Medicine) or a "human drug" (in which case it would be regulated by the FDA's Center for Drug Evaluation and Research).

In the end, the FDA regulated the genetically modified mosquito as a new animal drug. But that wasn't the end of the story, as Todd Kuiken, senior program associate at the Wilson Center's Synthetic Biology Project, told me. A similar product from the same company — a biopesticide for diamondback moths — that works using the same genetic technique was forwarded to the USDA for regulatory review rather than the FDA.

And, in some cases, synthetic biology is progressing so fast that there's simply not a regulatory agency that has clear jurisdiction over certain innovations. "The system is not flexible enough to address rapidly evolving technologies like synthetic biology," Kuiken says. "This could make it difficult for agencies to properly evaluate the potential risks of these products, as well making it difficult for products to move to the market."

This can happen in the cosmetics industry, for example, where commonly used cosmetic ingredients do not require FDA approval and companies are not required to label naturally occurring ingredients. This gets complicated, however, when synthetic biology innovators attempt to create a "synthetic" version of a commonly used, naturally occurring ingredient. Would they need to submit this for approval to the FDA or not?

Theoretically, squalene (a common ingredient in lotions) made from yeast microbes has the exact same chemical properties as squalene made from shark liver oil, so adding it to cosmetics products shouldn't trigger FDA regulatory action. The problem, however, is that adding a synthetic ingredient to cosmetics might trigger a requirement from the Federal Trade Commission for clear labeling of this ingredient.

And there are plenty more of these examples in the Wilson Center report – in fields ranging from pollution control to health care to agriculture to clean energy. A huge mining company using microbes to more effectively mine copper in hard-to-reach spots, for example, might run afoul of the TSCA (Toxic Substances Control Act), even if there's nothing particularly toxic about these microbes.

If similar types of innovations get caught in the regulatory maze of federal agencies, it could have a chilling effect on synthetic biology innovation, especially for smaller start-ups that may find the regulatory framework daunting. It all comes down to uncertainty: if you're a deep-pocketed investor,

would you invest millions of dollars in a company if you weren't sure that the company would be allowed to bring a new product to market within a reasonable period of time?

That obviously wasn't the case with Editas Medicine, which recently attracted $120 million in venture capital financing for its genome-editing technology, or Green Biologics, which recently landed $76 million for biofuels and bio-based chemicals. In fact, venture capitalists continue to back synthetic biology start-ups, to the tune of $500 million in the first nine months of 2015 – more than the total amount of synthetic biology VC financing in 2013 and 2014 combined.

So maybe the "chilling effect" produced by a complex regulatory landscape is overrated. In some cases, the approval process for synthetic biology innovations — especially those related to health and medicine — appears to be relatively straightforward, if at times arduous.

The real question seems to be about the type of innovations that are just so new or so revolutionary that government regulators get tripped up trying to define and understand them. In the recommendations section of the Wilson Center synthetic biology report, the authors noted several possible solutions: increasing funding to federal agencies, creating centers of technological excellence to keep regulators up-to-speed, and coming up with a long-term strategy that anticipates future changes within the industry. Think of this as making regulators smarter and better informed about how to approach new examples of synthetic biology innovation.

An important next step is to re-think the 1986 Coordinated Framework for the Regulation of Biotechnology, the core regulatory framework that lays out the regulatory responsibilities and statutes that apply to synthetic biology. However, this was last updated in 1992. What that framework assumes, then, is that the regulatory structures first put in place during the Reagan era are sufficient to address the scope of innovation nearly 30 years later.

The good news here is that the White House has recognized the need for change on the synthetic biology front. In July 2015, the White House issued a memo that suggested making changes to the framework in order to bring it up to date for modern realities. This fall, the White House Office of Science and Technology Policy began accepting comments on it and has scheduled the first public meeting to discuss a new Coordinated Framework on Oct. 30 at the FDA's White Oak Campus in Silver Spring, Md.

What's clear is that synthetic biology is another of those breakthrough technologies starting to make their way into the mainstream — alongside drones and self-driving cars — that regulators are struggling to understand. If they do, it could lead to a new era of progressive innovation. If they don't, it could stop the flow of new innovations to market and hand the lead to other nations that figure things out before the United States does.

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